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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/846,722	05/01/2001	Stanley E. Katz	CSI 1.0-005CIP	8104

7590 03/23/2004

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EXAMINER
TRAVERS, RUSSELL S

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 03/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/846,722	KATZ ET AL.	
	Examiner	Art Unit	
	Russell Travers, J.D.,Ph.D	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) *19-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18 and 27-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The response filed December 15, 2003 has been received and entered into the file.

The rebuttal arguments filed December 15, 2003 have been considered, but are unconvincing, Examiner notes the newly filed obviousness rejection is necessitated by Applicant's amendments

Claims 1-31 are presented for examination.

Applicant's election with traverse of group I in Paper No. 5 is acknowledged. The traversal is on the ground(s) that searching all presented inventions would not represent an undue burden to Examiner. This is not found persuasive because the presented inventions encompass a large therapeutic compound group not linked by structure, medicament class or biochemical effect. To search this broad functionally would place an undue burden on the Examiner.

The requirement is still deemed proper and is therefore made FINAL.

This application contains claims 19-26 drawn to an invention nonelected with traverse in Paper No. 5. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 19-26, reading on non-elected subject matter are withdrawn from consideration.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 1-12 and 27-31 are rejected under 35 U.S.C. § 103 as being unpatentable over Pandse et al, Robinson and Katz, in view of Lindstrom et al and Lueck.

Pandse et al, Robinson (see abstract and columns 1-2, lines 65-25) and Katz teach various pyruvate compounds and precursors as old and well known in combination with various pharmaceutical carriers and excipients in a dosage form. These medicaments are taught as useful for treating inflammation, viewed by the skilled artisan as immuno-suppressive, and possessing the therapeutic use herein claimed. Possessing these teachings, the skilled artisan would have been motivated to employ these compounds for any anti-inflammatory use, and enjoy a reasonable expectation of therapeutic success. Claims 1-12 and 27-31, and the primary references, differ as to:

1) recitation of salts, or related compounds.

2) the concomitant employment of these medicaments and carriers,

3) nasal administration of the medicaments, and,

4) disclosure of antimicrobial activity of the active agent

Possessing a compound for a therapeutic use, the skilled artisan possesses that compound□s analogs, homologs, isomers, salts, acids, esters and bioisosteres for the same therapeutic purpose.

It is generally considered prima facie obvious to combine therapeutic compounds, carriers and excipients each of which is taught by the prior art to be useful for the same purpose, in order to form a composition which is to be used for the very same purpose. The idea for combining them flows logically from their having been used individually in the prior art. As shown by the recited teachings, the instant claims define nothing more than the concomitant use of conventional anti-inflammatory agents, carriers and excipients. It would follow that the recited claims define prima facie obvious subject matter. Cf. In re Kerhoven, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980).

Lindstrom et al teach the excipients herein claimed as useful in formulating anti-inflammatory medicaments. The skilled artisan see the selection of one or another formulating agent as the simple selection from among obvious alternatives.

Claims 2 and 4-5 specifically requires an nasal pharmaceutical composition. Katz teaches the claimed compounds for treating inflammation in “body cavities and organs ... open to the environment” (see column 6). The skilled artisan would see this

teaching as inclusive of nasal passages. Nasal compositions, and the administration of therapeutic compounds nasally, would have been seen as residing in the skilled artisan's purview.

Lueck teaches the active agent polyethylene glycol as possessing antimicrobial activity, thus, inherently possessing the activity claimed.

Claims 10-12 are rejected under 35 U.S.C. § 103 as being unpatentable over Pandse et al and Robinson, in view of Merck Index.

Pandse et al and Robinson teach the claimed compounds as old and well known in combination with various pharmaceutical carriers and excipients in a dosage form. These medicaments are taught as useful for treating inflammation, viewed by the skilled artisan as immuno-suppressive, and possessing the therapeutic use herein claimed. Possessing these teachings, the skilled artisan would have been motivated to employ these compounds for any anti-inflammatory use, and enjoy a reasonable expectation of therapeutic success. Claims 10-12, and the primary references, differ as to:

1) the recitation of metabolite compounds, and

2) nasal administration of the medicaments.

Merck Index teaches the claimed pyruvate as the degradation product of propylene glycol, motivating the skilled artisan to employ this compound, or its degradation products for the same anti-inflammatory use.

Pandse et al and Robinson teach the claimed compounds for treating inflammation generally, and not limited to one specific anti-inflammatory use. Possessing this teaching, the skilled artisan would have been motivated to employ the

claimed anti-inflammatory compounds for nasal administration and enjoyed a reasonable expectation of therapeutic success, absent information to the contrary. Nasal compositions, and the administration of therapeutic compounds nasally, would have been seen as residing in the skilled artisan's purview.

Claims 13-18 are rejected under 35 U.S.C. § 103 as being unpatentable over Pandse et al, Robinson and Katz, in view of Lindstrom et al and Lueck, as set forth above, in further view of Hummel et al.

Hummel et al teach oxymetazoline as old and well known in combination with various pharmaceutical carriers and excipients in a dosage form. This medicament is taught as useful for treating rhinitis, viewed by the skilled artisan as indistinguishable from the use herein claimed. Possessing these teachings, the skilled artisan would have been motivated to employ this compound for any anti-rhinitis use, and enjoy a reasonable expectation of therapeutic success. Claims 13-18, and the primary references, differ as to:

1) the concomitant employment of these medicaments and carriers,

It is generally considered prima facie obvious to combine therapeutic compounds, carriers and excipients each of which is taught by the prior art to be useful for the same purpose, in order to form a composition which is to be used for the very same purpose. The idea for combining them flows logically from their having been used individually in the prior art. As shown by the recited teachings, the instant claims define nothing more than the concomitant use of conventional anti-rhinitis agents, carriers and

excipients. It would follow that the recited claims define prima facie obvious subject matter. Cf. In re Kerhoven, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980).

RESPONSE TO ARGUMENTS

Examiner notes repeated failed attempts to obtain the instant prior art references from Applicant. Internal problems at the Patent and Trademark Office resulted in these references being lost from the file. Examiner was unable to obtain the Pandse et al reference, thus, must soldier on with that information on the record. A new reference has been obtained, and employed in a new rejection. Absent the Pandse et al citation Examiner will assume those observations regarding the Pandse et al teaching are without error.

The instant claims read on employing a pyruvate precursor to treat the instant envisioned disease state. Examiner set forth propylene glycol as a pyruvate precursor, yet Applicant rejects this teaching. It is noted a textual reference was supplied to teach this bio-conversion, thus, the skilled artisan would be charged with this knowledge absent such disclosure by Examiner. That this compounds, propylene glycol, possesses anti-inflammatory activity is undisputed, thus, rendering the instant claims obvious over the prior art of record.

As the anti-inflammatory therapeutic effects of propylene glycol are undisputed, this compound would have been seen as a pyruvate precursor, albeit unanticipated by Applicant. Absent a negative limitation the skilled artisan would have seen this compound as obviating the claims are presented. Please note the instant claims fail to provide for a minimum effective level of therapeutic activity to practice the instant

claims. Thus, an agent possessing a scintilla of therapeutic activity would have been seen as meeting the activity requirements of the presented claims.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a). The practice of automatically extending the shortened statutory period an additional month upon the filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.
A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Travers, J.D.,Ph.D whose telephone number is 703-308-4603. The examiner can normally be reached on Monday to Thursday from 7:00 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, can be reached on 571-272-0629. The fax

phone number for the organization where this application or proceeding is assigned is 571-272-0631.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Russell Travers J.D., Ph.D.
Primary Examiner
Art Unit 1617